

June 27, 2014

To:

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Environmental Protection Agency
Washington, DC

(Sent via Federal eRulemaking Portal: [HTTP://www.regulations.gov](http://www.regulations.gov))

From:

The Herbicide Resistance Action Committee

Regarding:

Evaluation of 2,4-D Choline Salt Herbicide on Enlist Corn and Soybeans (Docket ID: EPA-HQ-OPP-2014-0195)

Introduction:

The Herbicide Resistance Action Committee (HRAC) is an industry-based group supported by Crop Life International that fosters a responsible approach toward herbicide use. The Committee's mission is to support and participate in research, conferences and seminars which serve to increase our understanding of herbicide resistance; to promote a better understanding of the causes and results of herbicide resistance; to communicate herbicide resistance management strategies and support their implementation through practical guidelines; and to seek active collaboration with public and private researchers, especially in areas of problem identification and implementing management strategies. HRAC is made up of representatives from BASF, Bayer Crop Science, Dow AgroSciences, Dupont Crop Protection, FMC, Makhateshim Agan, Monsanto, Syngenta, and Valent.

Our organization has reviewed the EPA's proposed registration of Enlist Duo Herbicide and is providing herein our comments on the proposed registration as it relates to herbicide resistance management (HRM). While many of the elements of the proposed registration will be helpful in HRM, there are a number of significant concerns that we have identified and that must be addressed in order for them to be successful. In the following pages, we highlight the areas of concern and provide suggestions for how those concerns may be addressed.

Summary Comments:

- The proposed registration will set a precedent for Herbicide Resistance Management Plans for future weed control products. Therefore, the proposed requirements must be broadly applicable to all herbicides and herbicide uses. Inconsistent implementation of requirements will likely drive farmers to products with the least onerous restrictions, placing increased selection pressure on those products. This ultimately would

exacerbate overall herbicide resistance and be counter to the common goal of preserving herbicide technologies and their use.

- EPA should consider issuing guidance on the general approach to HRM that it desires to see with herbicide registrations. This will provide important information to registrants in preparing their submissions. It will provide uniformity of approach and not a herbicide specific HRM recommendation. We believe that if the proposed approaches to HRM prove effective for this specific registration under consideration, they would also have utility more broadly for herbicide resistance management.
- Primary emphasis for investigation and reporting should be placed on suspected cases of new species found resistant to a given mechanism of action or particular product(s). This allows companies and university extension specialists to investigate management strategies for these new resistant species and provide recommendations in a timely fashion. Lesser effort should be devoted to investigation and reporting of resistance in species where resistance has become well established. Management practices for these species are usually well established and understood by growers.
- Methods of investigating non-performance claims vary by company, product, and geography. Regulatory guidance must consider these varying approaches and allow focus on suspected cases of new species found resistant and not previously reported resistant to a given MOA. For example, not every case of non-performance needs to be investigated by on-site visits but rather could be evaluated via phone interviews or electronic communication (email, video, etc.).
- Scouting is a HRM best management practice and should continue to be strongly recommended. However, the proposed *requirements* around scouting are too prescriptive and potentially impractical. Complicated scouting requirements will reduce farmer compliance and actually may reduce reporting of weed species populations suspected for resistance.
- Identification of a suspected, new, and previously undocumented resistant species should trigger implementation of best management practices to control the weed population and limit its spread. However, the requirement for eradication of resistant weeds is untenable as eradication means the complete elimination of the weed population an area including all growing plants and of seed in the soil.
- Management options for populations of concern should be developed on a case-by-case basis for the weed species, the location and whether or not resistance has been previously identified in the species.
- EPA should consider the practicality and impact of cancelling a specific registration, when other products with the same active ingredients are available. This may drive farmers to use less environmentally-friendly formulations and is unnecessarily punitive to farmers who rely on the product for weed control, have employed good WRM strategies, and do not have resistant weeds.

Section Comments

Proposed Registration pages 19-20

EPA Text:

IV. Resistance Management

The emergence of herbicide resistant weeds is an increasing problem that has become a significant economic issue to growers. This has led to a concern that the use of 2,4-D on GE crops may result in more resistant weeds. In an effort to address this issue going forward, EPA is requiring that DAS develop a stewardship program that will aggressively promote resistance management efforts.

HRAC Comment:

- The requirement for a stewardship plan that promotes herbicide resistance management efforts is acceptable.
 - The requirement should maintain the current flexibility that exists for herbicide providers to draft plans appropriate for the herbicide and the proposed herbicide use.
 - EPA could provide general guidance about the elements of a plan and should avoid being overly prescriptive in that guidance, thus allowing for plans that are locally appropriate for the herbicide and proposed herbicide use.
- A HRM stewardship plan could include:
 - **Label recommendations** for the herbicide use that are consistent with HRM best management practices (BMP's) and the inclusion of herbicide Mechanism of Action information on the label and the use of full labelled rates.
 - **HRM education activities** on weed management and herbicide resistance management, the herbicide use and how it fits with overall weed management goals.
 - **A product performance inquiry system** that the herbicide provider will use to monitor, identify and report weed populations suspected for resistance to the herbicide for species that have not been previously reported to have been selected for resistance.
 - **Adverse effects reporting** for confirmed cases of herbicide resistance as described under 6(a)(2).

EPA Text:

The overall goal of the stewardship plan is to assist and support responsible use of the product. With regard to weed resistance management, the plan mandates that DAS must immediately investigate any claims of non-performance. The initial mechanism users can use for communicating directly with DAS is a toll-free number to get advice on how to resolve any uncontrolled weeds.

HRAC Comment:

- We agree with EPA on the goal of the stewardship plan and investigating claims of non-performance in cases where herbicide resistance is suspected in a population of a weed species that has not been previously reported to have resistance.
- The proposed text is problematic in focusing on “immediate investigation” for “any” claim of non-performance. We recommend that EPA modify these statements for the following reasons:
 - Non-performance may be the result of many factors unrelated to herbicide resistance (e.g. applicator error, environmental factors, weed growth stage too large) and experience shows us that in the beginning of new resistance claims, a large proportion of weed control failures can be attributed to these.
 - Product non-performance inquiries must be handled quickly with the goal to control the emerged weeds as soon as possible. A dealer/applicator may make the decision to re-spray based on their knowledge of the weeds, field, and spray application before notifying the company that sells the herbicide.
- A proposed approach could include:
 - Investigate reports of product non-performance where populations may be suspected of herbicide resistance. Lack of performance is assessed against criteria to identify potential cases of herbicide resistance in a species in which resistance is previously unreported.
 - Take necessary action to manage populations of concern.
 - Further assess populations of concern to confirm whether or not the weed species is resistant to the herbicide.

EPA Text:

Academia, growers, USDA, and other leaders involved with pest management acknowledge the importance of field scouting. For this reason, the Enlist Duo™ label includes a requirement to scout treated fields. Field scouting before application will be essential to determining the weed species present as well as their stage of growth. Scouting 7-21 days after herbicide application will be used to assess the performance of weed control. In the event that a user encounters a non-performance issue, the toll-free number could be used to initiate an intervention against that weed population.

HRAC Comment

- We agree with EPA that field scouting is an important recommendation within the BMP's for HRM.
- The proposed text is problematic in focusing on very specific terms around scouting for the following reasons:
 - *Requiring* scouting is impractical and could potentially have a negative effect on the desire of farmers or applicators to report populations of concern for resistance. For example: If a farmer or applicator did not scout for reasons beyond their control, or did not scout within a prescribed timeframe- are they in violation of federal law? In these cases, a farmer or applicator would be less likely to report populations of concern.

- Enforcing the requirement for scouting and assessing the compliance with the scouting requirement would be practically impossible in US Agriculture.
- A proposed approach could include:
 - Continue to recommend scouting before and after treatment as part of the HRM-BMP's.
 - Provide guidelines as to the most useful post-treatment scouting time for assessment of efficacy and detection of potentially resistant populations.
 - Include the topic of scouting as part of education programs on HRM-BMP's.

EPA Text:

The DAS response to reports of non-performance must be immediate and must ensure that possible incidents of resistance are promptly investigated and resolved. EPA proposes that when a non-performance issue is identified, DAS or its representative will conduct a site visit and evaluate the issue using decision criteria identified by leading weed science experts (Norsworthy, et al.), in order to determine if “likely herbicide resistance” is present. This is distinct from, and more broad than, the term “likely herbicide resistance,” as explained below. For purposes of this decision, a report of non-performance to DAS will be the trigger for a site visit.

HRAC Comment

- We agree with EPA that a site visit is appropriate for instances when herbicide resistance is suspected in a weed species that has not been previously reported to have resistance to a particular herbicide. A site visit is not necessary for all product performance inquiries as many cases are resolved with the cause being some other factor than herbicide resistance. Cases requiring a site visit could be identified during communication concerning the product performance inquiry.
- We agree with EPA that assessing the population of concern against specific criteria to identify potential resistance is useful. *Norsworthy et al* is one source of criteria, but others may be useful as well, as long as the goal is to identify potential resistance by scientifically-based criteria.

EPA Text:

Non-performance refers to any cause that results in inadequate weed control after an herbicide application. “Lack of herbicide efficacy” refers to inadequate weed control with various possible causes, including but not limited to: application rate, stage of growth, environmental conditions, herbicide resistance, plugged nozzle, boom shut off, tank dilution, post-application weed flush, unexpected rainfall event, weed misidentification, etc. EPA recognizes that it can be challenging to determine emerging weed resistance at an early stage. Therefore, EPA is selecting criteria that it feels will be helpful to DAS and to users in identifying when instances of “lack of herbicide efficacy” in fact constitute “likely herbicide resistance.” These “likely herbicide resistance” criteria are: (1) failure to control a weed species normally controlled by the herbicide at the dose applied, especially if control is achieved on adjacent weeds; (2) a spreading patch of uncontrolled plants of a particular weed species; and (3) surviving plants mixed with controlled individuals of the same species (Norsworthy, et al., 2012).

HRAC Comment:

- We agree that criteria such as those presented in *Norsworthy, et al.* are useful to assess populations of concern for resistance.

EPA Text:

When DAS or its representative applies the Norsworthy, et al., criteria cited above and likely herbicide resistance is identified, then DAS must take immediate action to eradicate likely resistant weeds in the infested area. This may be accomplished by re-treating with an herbicide or using mechanical control methods. If herbicide re-treatment is used to eliminate the likely resistant weed(s), follow-up scouting will be required to confirm that the lack of herbicide efficacy has been resolved. DAS must also notify EPA that likely herbicide resistance has been identified and report this on a monthly basis. In addition, samples of the likely herbicide resistant weeds and/or seeds must be taken, and prior to the next growing season laboratory or greenhouse testing must be initiated in order to determine whether resistance is the reason for the lack of herbicide efficacy. DAS must also work to develop a laboratory diagnostic test to quickly identify herbicide resistance, and report to EPA its progress toward developing such a diagnostic test.

In addition to reporting incidents of likely resistance, on or before October 15 of each year, DAS will submit annual summary reports to EPA. These reports must include a summary of the number of instances of likely and confirmed resistance to Enlist Duo™ by weed species, crop, county and state. They will also summarize the status of laboratory or greenhouse testing for resistance, as well as the status of the development of a laboratory test. The annual reports will also address the disposition of incidents of likely or confirmed resistance reported in previous years.

HRAC Comment:**HRAC agrees:**

- That while action must be taken to manage suspected resistant weed populations that have not been previously reported to have resistance, educational efforts to get farmers to implement proactive BMPs must be the primary effort.
- That follow-up on the site with the population of concern is needed
- That reporting to EPA on populations of a weed species that has not been previously reported to have resistance would be acceptable. The frequency of this reporting should be re-evaluated. Reporting could be accomplished by various mechanisms including but not limited to:
 - Identification of populations of concern, follow-up on those populations, and confirmation of resistance, reported annually.
 - Confirmed cases of resistance – currently in place under adverse effects 6(a)(2) reporting.

- Continued reporting of confirmed resistant populations through the International Survey of Herbicide Resistant Weeds (available at: www.weedscience.org)
- Parts of the requirements as written in this section are problematic or impractical when considering production agriculture, land ownership and weed biology. These include:
 - The requirement for eradication is untenable and will be impossible to practically implement or enforce. Eradication is the complete removal of the weed species. Weed seeds can remain viable in the soil seed bank for many years. A farmer would be in violation of the law if a new resistant population remains on their farm.
 - The decision to manage a resistant population is made by the grower. Companies can make recommendations but the ultimate action taken is up to the grower. What will EPA do with the information in monthly reports? There will be reluctance on the part of growers to report resistant weed populations if this information becomes publicly available.
- Development of a specific diagnostic test may be impossible. There are multiple mechanisms known to confer resistance to herbicides depending upon the weed species, and the herbicide. Unique diagnostic tests would likely be required for each species & each resistance mechanism.

EPA Text:

Several management practices that are designed to help users avoid initial occurrences of weed resistance will appear on the product labeling under the Resistance Management heading of the label. These practices are discussed in Section VII.B.3 of this document.

HRAC comment

- We agree that best management practices for HRM should be on the herbicide label.

Pp 29-31

EPA Text

1. Stewardship Program

EPA has determined that the registration must contain a term that requires DAS to have a stewardship program for Enlist Duo™. DAS has begun developing its program which it states is focused on educating and training retailers, farmers and applicators on the appropriate use of the Enlist™ technology. EPA has determined that the stewardship program must include the following measures (also to be included as terms on the registration) that would minimize the potential for off-target movement and avoid the development of weed resistance.

a. Investigation

EPA has determined that the registration must contain a term that requires DAS or its representative to investigate reports of non-performance as reported by users following required “scouting” (in accordance with labeling requirements). When investigating these

reports, DAS or its representative would be required to conduct site visits.

b. Reporting of the Incidence of Likely Herbicide Resistance

EPA has determined that the registration must contain a term that requires DAS to use the Norsworthy criteria for determining likely herbicide resistance and inform EPA if likely resistance has been identified. This information must be submitted to the Agency on a monthly basis.

c. Remediation

EPA has determined that the registration must contain a term that requires DAS to take immediate action to eradicate likely resistant weeds in the infested area as well as requiring DAS to collect material for further testing.

d. Annual Reporting of Herbicide Resistance to EPA

EPA has determined that the registration must contain a term that requires DAS to submit annual summary reports to EPA that include a summary of the number of instances of likely and confirmed weed resistance by weed species, crop, county and state. The annual reports must include summaries of the status of laboratory or greenhouse testing for resistance. The annual reports would also address the disposition of incidents of likely or confirmed resistance reported in previous years. These reports would not replace or supplement adverse effects reporting required under FIFRA 6(a)(2).

e. Reporting of Likely Resistance to other Interested Parties

EPA has determined that the registration must contain a term that requires DAS to inform growers and other stakeholders of likely and confirmed resistance to Enlist Duo™. The information will include details of weed species and crop. EPA understands that DAS already plans to provide this information through a devoted website.

f. Reporting on the development of diagnostic tests

EPA has determined that the registration must contain a term that requires that DAS would inform EPA of DAS's progress toward diagnostic testing for evaluating resistant weed species.

g. Monitoring the use of Enlist Duo™ on Enlist™ Seed

EPA believes it is important to require DAS to monitor whether Enlist Duo™ is being used on the Enlist™ seed purchased from DAS. EPA has determined that the registration must contain a term that requires DAS to provide EPA with a protocol to survey whether Enlist Duo™ is being used on Enlist™ seed purchased from DAS and not the non-choline 2,4-D products that are not registered for these application windows. EPA expects that a protocol would be agreed upon quickly so that monitoring the use of Enlist Duo™ can begin shortly thereafter.

h. Training and Education

EPA has determined that the registration must contain a term that requires DAS to provide training on the use of Enlist Duo™ when it provides training on the Enlist™ Seed technology. The training would focus on proper use of the technology to avoid off-target movement as well as avoid weed resistance.

2. EPA's Continued Control over the Registration

Because the issue of weed resistance is an extremely important issue to keep under control and can be very fast moving, EPA has determined that the registration must contain terms that ensure that EPA retains control to easily and quickly modify or cancel the registration if necessary.

3. Geographic Limitation on Use of Enlist Duo™

EPA has determined that Enlist Duo™ would be allowed to be sold and used only for those states for which an endangered species assessment has been completed and resulted in a “no effect” determination. Currently, the states of Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin have been found to comply with these criteria. Additional states may be added to the labeling if assessments for those states are completed and demonstrate that a “no effects” determination is appropriate.

HRAC Comment

- EPA needs to assess the market effect and impact on economic viability, of quickly cancelling a registration on growers who have sensitive weed populations.
- Cancelling registrations for a given product will not address resistance problems given that multiple products with the active ingredients or products with the same MOA are available. Cancellation of registrations due to herbicide resistance must be carefully considered. In many cases, there are many additional susceptible weed species that may not be controlled effectively by other herbicides.

We appreciate EPA's consideration of these comments for the proposed registration of Enlist Duo Herbicide.

On behalf of the Herbicide Resistance Action Committee,

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